

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

• **BLACK BORDERS**

- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

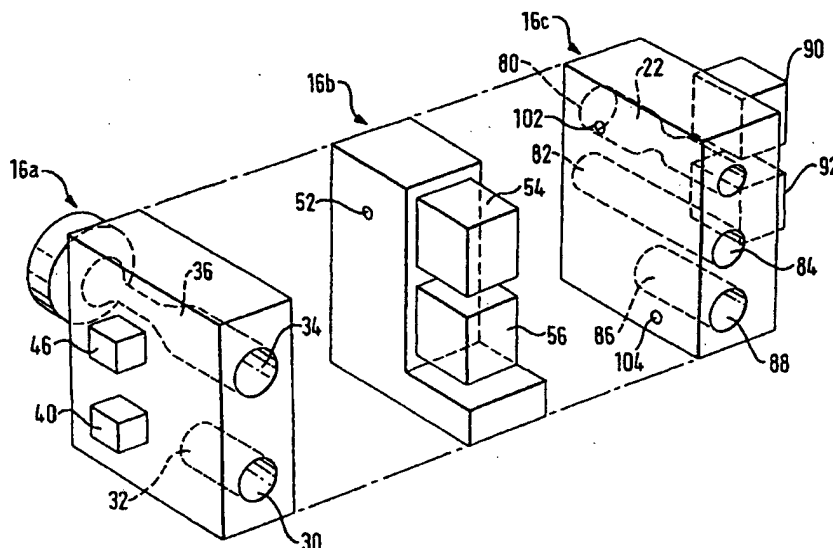
**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61B 18/02, F16K 27/00, F25B 9/02</p>	<p>A2</p>	<p>(11) International Publication Number: WO 00/35362</p> <p>(43) International Publication Date: 22 June 2000 (22.06.00)</p>
<p>(21) International Application Number: PCT/GB99/04110</p> <p>(22) International Filing Date: 7 December 1999 (07.12.99)</p> <p>(30) Priority Data: 9827510.0 14 December 1998 (14.12.98) GB</p> <p>(71) Applicant: SPEMBLY MEDICAL LIMITED [GB/GB]; Newbury Road, Andover, Hampshire SP10 4DR (GB).</p> <p>(72) Inventors: COPPING, Gareth; Hunters Hill, 20 Lilywhite Crescent, Andover, Hampshire SP10 5NA (GB). COLEMAN, Richard; 44 Roman Road, Salisbury, Wiltshire SP2 7BJ (GB).</p> <p>(74) Agents: HOLMES, Miles, Keeton et al.; D Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).</p>		<p>(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>Without international search report and to be republished upon receipt of that report.</i></p>

(54) Title: CRYOGEN SUPPLY APPARATUS



(57) Abstract

A cryogen supply unit is disclosed for controlling the flow of a Joule-Thompson fluid through a cryosurgical instrument. The supply unit includes a fluid flow path manifold block (16) formed as an assembly of three sub-units (16a, 16b, 16c). The manifold block includes internal fluid passageways and carries functional devices including pressure regulators (36, 82), open/closed valves (54, 56, 90, 92), connector sockets (30, 22, 86) and fluid pressure sensors (40, 46). The manifold avoids the need for conventional floating or suspended tubes to link the functional devices. A defrosting method is also described for defrosting the Joule-Thompson instrument by applying generally equal pressures of cryogen fluid to the inlet and exhaust channels of the instrument.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

1

CRYOGEN SUPPLY APPARATUS

FIELD OF THE INVENTION

The present invention relates to apparatus for use in controlling the flow of cryogenic fluid through a cryosurgical instrument, such as a cryosurgical probe, to produce, for example, cooling or defrosting effects. The invention is especially suitable for supplying cryogen gas which produces cooling within the instrument by a Joule-Thompson (J-T) throttling effect, but the invention may be used with other fluid supplies.

DESCRIPTION OF PRIOR ART

Typically, the flow of cryogenic fluid is controlled by means of a control unit or console to which the cryosurgical instrument is coupled by inlet and exhaust lines. The console may include an internal supply of cryogen fluid, or it may be coupled to an external supply. For a J-T system, a replaceable bottle supply of high pressure gas is commonly used.

The control console includes regulators, valves and one or more pressure sensors, to control the pressure of the gas supplied to the instrument, and to allow different modes of operation, such as pre-freeze purging, freeze, and defrost. The regulators, valves and pressure sensors are coupled together within the console by floating or suspended tubing, to form a fluid flow circuit. Where junctions are necessary, a junction piece is interposed between two pieces of tubing.

In devising one aspect of the present invention, it has been appreciated that the above prior art construction is relatively complicated, requires a large number of fluid-tight tube joints to be made, and is vulnerable to leaking at any of the fluid joints. This is especially true for high pressure portions of the fluid circuit in a J-T system, in which the fluid pressure will typically be about 750 psi. This results in the console being relatively expensive to construct, and difficult to maintain. The console may also require particularly careful handling and transportation, to avoid creating leaks or weakening the joints between the suspended tubing.

The present invention has been devised bearing the above in mind.

SUMMARY OF THE INVENTION

In contrast to the above prior art, one broad aspect of the present invention is to employ a fluid circuit manifold having a plurality of fluid flow paths, and carrying at least one functional device communicating with an internal fluid flow path.

5 As used herein, the term "functional device" covers broadly any device for controlling, directing, handling, or sensing, fluid flow in a flow path. For example, the term includes devices such as valves (e.g. open/closed valves, or variable aperture valves), regulators (e.g. fixed pressure regulators or variable pressure regulators), sensors (e.g. pressure sensors or temperature sensors), and inlet and outlet connectors.

10 As used herein, the term "manifold" covers broadly any integral structure defining a plurality of flow paths. The structure may itself be an assembly of sub-units coupled together to form an integral structure, provided that the sub-units do form an integral unit.

The invention can provide significant advantages over the prior art, by
15 reducing the number of couplings required in the fluid circuit, and therefore reduce the number of potential leak points in the system. The manifold may also provide a convenient mounting for the one or more functional devices, and can avoid the need for suspended tubing between the devices. This can reduce manufacturing costs, and provide a more durable product with improved reliability.

20 Although manifolds are known in certain engineering applications, such a system has not been proposed hitherto for use in the present highly specialised field of cryogen fluid control, in particular for providing a cryogenic fluid circuit, and for carrying one or more functional devices. Moreover, such a system has not been proposed for handling high pressure J-T cryogen fluids.

25 In one preferred form, the manifold is in the form of a block, which is drilled and/or otherwise machined to define internal passageways, and mounting ports and/or apertures for the functional devices.

It may be convenient to form the manifold as a plurality of sub-units or modules, which are then secured together to form the overall manifold unit. Once
30 assembled, the sub-units are rigidly fixed to each other, and it is very rare to have to

disassemble the manifold. This means that the seals between the sub-units will not be prone to leakage, and will not deteriorate as a result of movement or repeated disassembly.

Preferably, the manifold (or manifolds if more than one manifold is used) defines at least the majority of a fluid circuit within the console, and supports at least the majority of the functional devices for the fluid circuit. In an especially preferred form, the manifold carries all of the fluid circuit functional devices.

Another aspect of the invention addresses the problem of generating rapid re-heating (also referred to as "defrosting") of a cryosurgical instrument after the instrument has been operated during a freeze cycle. Various techniques are known in the art, including back flushing gas through the cryosurgical instrument, or allowing natural re-heating, or using an electric heater to heat the instrument.

It would be desirable to provide a re-heating system which is versatile, yet simple to implement, and which does not require a large number of additional system components.

In accordance with this aspect, the invention provides a unit in which is operable to re-heat a J-T cryosurgical instrument by application of generally equal pressures of fluid to the inlet and exhaust channels of the instrument.

With such a system, defrosting or reheating is achieved by the gas in the exhaust channel being re-pressurised, and generating heat. The defrost action is achievable extremely quickly by application of relatively high pressure gas, for example, more than 300 psi, to both the inlet and exhaust channels of the instrument.

It will be appreciated that the defrost feature can be implemented very conveniently in a conventional J-T system. In a preferred form, the system includes a valve means operable to couple together the inlet and exhaust channels of, or to, the cryosurgical instrument, and to cut-off the normal exhaust vent (for example, an atmospheric vent).

In a closely related aspect, the invention provides a control unit for controlling the flow of cryogen fluid through a cryosurgical instrument cooled by the Joule Thompson effect, the control unit comprising first and second fluid path channels for

coupling to the cryosurgical instrument, and being operable in a first operating mode to supply pressurised cryogen fluid to the first channel and to exhaust expended fluid from the second channel, and being operable in a second operating mode to supply pressurised cryogen fluid to both the first and second channels at substantially equal pressures.

In a closely related aspect, the invention provides a control unit for controlling the flow of cryogen fluid through a cryosurgical instrument cooled by the Joule Thompson effect, the control unit comprising a fluid flow path circuit comprising:

- an inlet for receiving pressurised cryogen fluid;
- 10 a coupler for coupling first and second fluid path channels to a cryosurgical instrument;
- an exhaust outlet for exhausting expended fluid; and
- valve means operable: in a first operating mode to couple the inlet to the first channel of the coupler, and to couple the second channel to the exhaust outlet; and in
- 15 a second operating mode to decouple the second channel from the exhaust outlet, and to couple the inlet to the first and second channels of the coupler.

Preferably, the control unit includes valve means for selectively coupling the inlet to the first channel of the coupler.

Preferably, the control unit includes a pressure regulator for regulating the fluid pressure received through the inlet.

Preferably, the control unit comprises an electronic control circuit for controlling the operation of the valve means.

In a yet further related aspect, the invention provides a method of operating a cryosurgical instrument, the instrument including first and second channels and a throttling constriction for generating cooling by Joule Thompson expansion of gas passing through the constriction from the first channel to the second channel, the method comprising:

during a cooling cycle, applying pressurised cryogen to the first channel, and exhausting expanded cryogen from the second channel; and

5

during a re-heat (defrost) cycle following the cooling cycle, applying generally equal pressures of cryogen fluid to the first and second channels.

Preferably, the defrost cycle follows the cooling cycle immediately.

Preferably, the method further comprises a venting cycle following the re-
5 heating cycle, in which the first and second channels are vented at generally the same rate as each other. Preferably, this is achieved by allowing the first and second channels to be coupled together while they are vented.

DESCRIPTION OF THE DRAWINGS

Embodiments of the invention are now described by way of example only,
10 with reference to the accompanying drawings, in which:

Fig. 1 is a schematic view of a J-T control console;

Fig. 2 is a schematic front view of the fluid manifold of the console;

Fig. 3 is a schematic exploded rear view of the fluid manifold showing the functional devices (but not showing internal fluid flow paths);

15 Fig. 4 is a schematic rear view of a first part of the manifold;

Fig. 5 is a schematic side view of the first part of the manifold;

Fig. 6 is a schematic rear view of a second part of the manifold;

Fig. 7 is a schematic side view of a third part of the manifold;

Fig. 8 is a schematic rear view of the third part of the manifold;

20 Fig. 9 is a schematic fluid flow diagram showing the fluid circuit in each part of the manifold;

Fig. 10 is a schematic diagram illustrating the sealing arrangement between the manifold parts;

25 Fig. 11 is a schematic section through the tip of a typical J-T cryosurgical probe;

Fig. 12 is a partial schematic diagram showing an alternative arrangement of valves;

Figs. 13 and 14 are logic tables showing the valve states during the different operating modes;

Fig. 15 is a schematic section showing a constriction within a port of the manifold block;

Fig. 16 is a partial schematic diagram showing a yet further arrangement of valves;

5 Fig. 17 is a partial schematic diagram showing a modified valve arrangement; and

Fig. 18 is a rear perspective view of a one-piece manifold.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1 of the drawings, a control console 10 for a J-T cryosurgical
10 system includes a case 12 containing an electronics module 14 and a fluid flow circuit defined by a manifold block 16. An inlet conduit 18 supplies high pressure fluid, for example, nitrous oxide from an external source (not shown) to the rear of the manifold block 16. A variable pressure regulator (described below) is mounted within the block 16, and is controlled by a manually operable rotary control 20 projecting from
15 the front of the block 16 through the front panel of the case 12. The block 16 also carries a socket 22 for coupling to a cryosurgical instrument (not shown), to supply fluid to the instrument, and to receive exhaust gas from the instrument. The socket projects from the front of the block, through the front panel of the case 12. The expended exhaust gas exits the block 16 through an atmospheric exhaust line 24
20 coupled to the rear of the block 16.

As described in detail below, the manifold block 16 contains internal fluid passages, and carries various functional devices (including the variable pressure regulator) to form a multi-functional fluid circuit, to enable the console 10 to operate in various functional modes.

25 Referring to Figs. 2 and 3, in this embodiment, the manifold block 16 is formed by three sub-units 16a, 16b and 16c. Splitting the block into sub-units can enable more intricate configurations of fluid passages to be machined in each sub-unit, to form an overall path configuration which might be virtually impossible to produce from a single unit manifold block. It can also facilitate modular assembly and testing
30 of the different sub-units 16a-16c if desired.

In this embodiment, the sub-units are made from solid aluminium, which is relatively easy to machine. Figs. 3-8 show the internal flow paths within each sub-unit. These flow paths can be drilled or otherwise machined in the aluminium blocks after the blocks have been shaped. Some of the flow paths are depicted in the drawings as not extending to an exterior surface of the block. The skilled man will appreciate that such flow paths in a block are formed by extending the path to the surface of the block, and subsequently fitting a plug to close the unwanted opening in the exterior surface. However, for the sake of clarity, such extensions and plugs are not shown explicitly in the drawings; only the "functional" flow paths interconnecting various functional devices are illustrated.

The first sub-unit 16a (Figs. 2 to 5 and 9) is generally rectangular, and comprises a rear inlet aperture 30 for receiving an input particulate filter/connector 32 for communicating with the high pressure inlet conduit 18. The first sub-unit 16a also includes a second through aperture 34 for receiving the variable pressure regulator 36. The apertures 30 and 34 communicate via a first internal passage 38 to supply input fluid from the input connector 32 to the regulator 36.

In order to monitor the pressure of fluid entering the block 16 in this embodiment, an optional inlet pressure sensor 40 is mounted externally on the side of the first sub-unit 16a. The inlet pressure sensor 40 is threadedly engaged in a threaded bore 42 which communicates with the inlet aperture 30 by a second internal passage 44. The inlet pressure sensor 40 is provided to monitor whether the inlet pressure exceeds a certain minimum threshold, for example, 600 psi. It will be appreciated that if the inlet pressure falls below a certain threshold, then it may be impossible to generate a sufficient cooling effect in the cryosurgical instrument. The electronics control module 14 monitors the output from the inlet sensor 40, and generates a warning signal should the pressure be too low for normal operation. The inlet sensor 40 may, for example, be a pressure switch, or a variable output transducer.

If desired, the inlet pressure sensor 40 may be omitted, and the second pressure sensor 46 used as a sole sensor for monitoring the gas pressure.

In order to monitor the output pressure from the regulator 36, a second pressure sensor 46 is mounted externally on the side of the first sub-unit 16a, above the inlet pressure sensor 40. The second pressure sensor 46 is threadedly engaged in a bore 48 which communicates directly with the aperture 34 housing the regulator 36. The output from the second sensor 46 is fed to the electronics module to provide a visual indication of the output pressure on the console front panel.

The fluid output from the first sub-unit 16a of the block 16 exits through a bore 50 which is aligned with a complementary input bore 52 in the opposing face of the second sub unit 16b.

The second sub unit 16b (Figs. 2, 3, 6 and 9) is generally L-shaped, and carries two externally mounted, electronically controlled open/closed valves, referred to as a freeze valve 54 and a purge valve 56; the terminology refers merely to the operating modes of the console, the valves operating here merely to control the routing of fluid through the second sub-unit. The input bore 52 leads to the freeze valve inlet port 58 on the surface of the second sub-unit 16b, and in parallel via a third internal passage 60 to the purge valve inlet port 62 on the surface of the sub-unit 16b.

Adjacent to the freeze valve inlet port 58 is a freeze valve outlet port 64 for receiving fluid passed by the freeze valve 54 when the valve is open. The freeze valve outlet port 64 is coupled by a fourth internal passage 66 to a first outlet 68 to the third sub-unit 16c.

Adjacent to the purge valve inlet port 62 is a purge valve outlet port 70 for receiving fluid passed by the purge valve 56 when the valve is open. The purge valve outlet port 70 is coupled by a fifth internal passage 72 extending into the base of the "L" shape, to a second outlet 74 to the third sub-unit 16c.

The valves 54 and 56 are mounted on the rear surface of the second sub-unit 16b in alignment with the pairs of ports 58 & 64, and 62 & 70, respectively. The valves are retained in position by bolts extending into threaded holes 76 in the rear surface of the second sub-unit 16b.

The third sub-unit 16c (Figs. 2, 3, 7, 8 and 9), has a rectangular shape similar to the first sub-unit 16a. Internally, the third sub-unit 16c carries the instrument

connector socket 22 in a connector through aperture 80. It also carries an internal fixed regulator 82 mounted within a through aperture 84, and an internal exhaust socket 86 mounted within a rear aperture 88.

Externally mounted on the side of the third sub-unit 16c are two further
5 electronically controlled open/closed valves, referred to herein as a defrost valve 90 and an exhaust valve 92. As before, the terminology refers to the operating modes of the console. Each valve is aligned with an inlet port 94, 96 respectively, and an output port 98, 100, respectively, on the side surface of the third sub-unit 16c. The valves are secured in position by bolts received in threaded holes 76 in the side surface of the
10 third sub-unit 16c.

On the side face of the third sub-unit 16c facing the second sub-unit 16b are a first inlet bore 102 and a second inlet bore 104 aligned respectively with the first outlet 68 and the second outlet 74 of the second sub-unit 16b. The first inlet bore 102 leads directly into the connector aperture 80 to communicate with the supply port of
15 the connector socket 22 (i.e. to communicate with the supply line to the cryosurgical instrument).

The second inlet bore 104 is coupled by a sixth internal passage 106 to the inlet to the fixed pressure regulator 82. The output from the fixed pressure regulator 82 is coupled by a seventh internal passage 108 also to the supply port of the
20 connector socket 22. There are therefore two parallel fluid paths through the second and third sub-units 16b and 16c, to the supply port of the instrument socket. The first is a high pressure, or "freeze" path through the freeze valve 54. The second is a low pressure, or "purge" path through the purge valve 56, and through the fixed (low) pressure regulator 82.

25 The exhaust port of the instrument socket 22 is coupled by an eighth internal passage 110 to the input port 96 for the exhaust valve 92. The output port 100 for the exhaust valve communicates directly with the exhaust connector 86 in the rear exhaust aperture 88, to allow the flow of exhaust gas from the manifold block 16 when the exhaust valve 92 is open.

10

A ninth internal passage 112 couples the input port 96 for the exhaust port 92 to the input port 94 for the defrost valve 90. The output port 98 for the defrost valve 90 communicates directly with the supply port of the instrument connector (in parallel with the first inlet bore 102 and the seventh internal passage 108). It can be seen that
5 the defrost valve 90 is therefore operative, when open, to couple together the supply and exhaust ports of the instrument socket 22, and thereby to equalise the pressure on the delivery and exhaust sides of the J-T cooling nozzle within the cryosurgical instrument.

The manifold block sub-units 16a-16c are secured together by bolts. In the
10 present embodiment, the first and third sub-units are attached independently to the second sub-unit. The first sub-unit 16a includes counter-sunk through bores 120, and the second sub-unit 16b includes threaded holes 122 for receiving bolts inserted through the bores 120. The third sub-unit 16c similarly includes counter-sunk through bores 124, and the second sub-unit 16b includes threaded holes 126 for receiving bolts
15 inserted through the bores 124.

The fluid connections between the first and second sub-units 16a and 16b, and between the second and third sub-units 16b and 16c, are rendered fluid-tight by means of a sealing arrangement illustrated in Fig. 10. One of the faces is machined to have a small annular pocket 130 encircling the bore, and a resilient O-ring 132 is placed
20 within the pocket. A bridging tube or spigot 134 is inserted within the O-ring 132. When the two faces are tightened against each other, the O-ring 132 is compressed to form a highly reliable seal. The pocket 130 provides a seat for the O-ring, and the tube 134 serves to prevent the O-ring from deforming inwardly, which might block or constrict the fluid path. Such a sealing arrangement is simple and inexpensive, yet
25 can provide a perfect seal even for high fluid pressure. The seal is located within the manifold block 16, and it is very rare that the sub-units of the manifold block will be separated or moved relative to each other after the initial construction. Therefore, the seal life will not be reduced by external forces or by repeated disassembly or adjustment of the seal.

A circular spot face 136 is also used to provide a good sealing surface around the pocket 130. Spot faces 138 are also used around each of the ports 58, 62, 64, 70, 94, 96, 98, 100 to provide sealing surfaces to co-operate with the seals built into the valves 54, 56, 90 and 92.

5 An important feature of this embodiment is that the seals for the valves 54, 56, 90 and 92 are not integral with the manifold 16. This is different from conventional design practice in the field of cryosurgery, in which the seals are normally formed in the external connectors to the valves. This feature in the present embodiment can enable a defective valve to be replaced without having to charge or dismantle the
10 manifold. It will be appreciated that if the manifold, or a sub-unit, had to be replaced, this would make repair of the unit very expensive. The valve seals may either be integral with the valves themselves (as described above) or they may be separate replaceable items.

In use, the valves 54, 56, 90 and 92 are controlled by the electronics module
15 14 to provide different console operating modes. The electronics module 14 typically includes a microprocessor or microcontroller (not shown) executing a software control routine, to control the electronic signals sent to the valves.

The different operation modes of the console 10 can be best appreciated from Fig. 9. In this figure the broken lines represent the boundaries between the different
20 sub-units 16a-16c of the manifold block 16.

The valve states in the different operating modes are shown in Fig. 13. States indicated in parentheses are not critical for that mode (e.g. if other valves have a dominating effect), but are preferred as a fail-safe. For the avoidance of doubt, the term "open" is used herein to mean that the valve allows the passage of fluid
25 therethrough, and the term "closed" is used herein to mean that the valve substantially blocks the passage of fluid therethrough.

In a passive or vent mode, the freeze valve 54 and the purge valve 56 are closed, while the defrost valve 90 and the exhaust valve 92 are open. In this mode no fluid is passed to the cryosurgical instrument. The open exhaust valve 92 means that
30 the system is always vented to atmosphere when vented, and the open defrost valve 90

ensures that the inlet side of the cryosurgical instrument is not pressurised. This is the default fail-safe mode of the console, and so normally-closed valves are used for the freeze valve 54 and the purge valve 56, while normally-open valves are used for the exhaust valve 92 and the defrost valve 90. However, it will be appreciated that, if
5 desired, the defrost valve may be closed during the vent cycle if it is considered unnecessary to provide such a failsafe.

In a purging mode, the freeze valve 54 and the defrost valve 90 are closed, but the purge valve 56 is opened to match the state of the exhaust valve 92. During this phase low pressure fluid is supplied to the cryosurgical instrument, and is exhausted
10 through the atmospheric exhaust output. The low pressure gas serves to remove any residual moisture in the cryosurgical instrument, prior to freezing. The low pressure is created by the fixed pressure regulator 82 through which the fluid is routed by the purge valve 56. (It will be appreciated that the fluid pressure is normally about 750 psi, but this is reduced to a much lower pressure of about 150 psi (or 300 psi) by the
15 fixed regulator 82).

To enter the freeze mode, the purge valve 56 is closed, and the freeze valve 54 is opened to allow full-pressure fluid to pass to the cryosurgical instrument. The defrost valve 90 remains closed, such that the expanded gas exits the manifold through the exhaust channel.

20 After freezing has been completed, the defrost mode is entered by closing the exhaust valve 92, and opening the defrost valve 90. During this cycle, the freeze valve 54 remains open to supply high pressure gas to the instrument socket. The effect of the open defrost valve 90 is to apply the high pressure fluid simultaneously to both the supply and exhaust sides of the cryosurgical instrument. This equalises the
25 pressure causing a rapid warming effect by re-pressurisation of the expanded gas on the exhaust side of the J-T nozzle within the cryosurgical instrument.

After defrosting, the freeze valve 54 is closed, and the exhaust valve 92 opened to vent the fluid within the system. During this venting, the defrost valve 90 may be kept open to ensure that no significant pressure is developed between the
30 supply and exhaust sides of the J-T nozzle;

Various defrost techniques are known in the prior art, including back flushing warm gas through the cryosurgical instrument. However, back flushing can cause complications. For example, Fig. 11 illustrates a typical J-T probe tip. The probe includes concentric inner and outer walls 140 and 142, defining an inlet channel 144 and an exhaust channel 146 in the probe. The inner wall 140 is crimped near its tip to form a constriction 148. During freezing, the J-T throttling effect takes place at the constriction 148 as high pressure gas is forced through the constriction and expands in the probe tip. The expanded gas then exits through the exhaust channel 146.

It will be appreciated that if gas is backflushed through the probe at any significant rate (required for rapid defrosting), the backflushed gas will itself undergo J-T throttling as it passes through the constriction 148. Therefore, the act of backflushing will itself create cooling, which is contrary to the defrost function, and reduces the defrost efficiency.

Compared to prior art techniques, the defrost feature used in the preferred embodiment described above can provide rapid and efficient defrosting without the problem of cooling being generated by gas flow through the constriction 148. Once the cryogen pressures have equalised, the equal pressures of cryogen fluid in the inlet and exhaust channels 144 and 146 ensures that there is negligible flow through the constriction.

If the defrost valve is set open during the venting cycle, then it will be also be appreciated that (following the defrost cycle) the open defrost valve 90 would maintain equal pressures in the inlet and exhaust channels of the instrument, and prevent any recooling. Depending on the situation, re-cooling might sometimes be undesirable. However, it will be appreciated that in a normal operating procedure, the probe will have been removed from contact with a patient at the stage when the system is vented. Therefore, it is not expected that accidental re-cooling during venting will in practice cause any problems, and it is not considered essential that in all embodiments the defrost valve be set open during the vent cycle.

In some cases, it may be desirable to provide some flow of fluid through the instrument during the defrost cycle, instead of rapid, instant pressure equalisation. This has been found to increase the defrost efficiency.

One technique for providing limited flow is to include a resistance, or
5 restrictor (shown schematically at 138 in Fig. 9) in series with the defrost valve 90. Such a restrictor may, for example, be formed by a constriction in the flow path; in one embodiment a constriction to 12 thousands of an inch (approximately 0.3 mm) in a bore passage normally of 3 mm in diameter has been used. Referring to Fig. 15, a preferred technique for including such a small constriction is to machine the
10 constriction 160 in an insert 162 which is slid into one of the ports 98 or 112 for the defrost valve 90. The insert 162 is held in position by sitting against a shoulder 164 within the port. Such an arrangement allows the insert 162 to be removed if required (e.g. in case of blockage, or repair).

The effect of the restrictor is to slow the rate at which high pressure fluid is fed
15 through the defrost valve 90 into the exhaust channel of the instrument to equalise the pressures. This maintains some flow of fluid through the instrument for a period of a few seconds, such that the re-pressurisation (and hence re-heating) of the probe occurs over a period of a few seconds.

An alternative technique for providing limited flow during defrost is to
20 provide a leaky exhaust path 139 in parallel with the exhaust valve 92. As illustrated in Fig. 9, the path 139 (if provided) may include a resistance, or restrictor (e.g. a constriction) 138a to limit the flow through the path 139. The effect of the leaky exhaust path 139 is to make the exhaust valve 92 "leaky", such that there will be a very small flow of fluid from the probe to provide improved defrost performance.
25 The leaky path may, for example, be formed by drilling a very fine hole between the ports 96 and 100 for the exhaust valve 92, or by using an insert (similar to the insert 162 of Fig. 15) arranged in a bore (not shown) joining the ports 96 and 100.

The resistance 138 in the defrost path, and the leaky exhaust path 139, may be used as alternatives to each other, or together in combination. For probes having a
30 normal cryogen flow rate of up to about 10-15 litres/minute, it is envisaged that either

15

technique might be suitable individually. However, for probes having a greater cryogen flow rate (say about 20 litres/minute or higher), then it is preferred that both techniques be used in combination.

Fig. 12 illustrates an alternative valve arrangement to replace the freeze valve 54 and the purge valve 56 in the second sub-unit 16b of the manifold (it being appreciated that a different design of conduits within the manifold would be required to accommodate this alternative circuit). Instead of using a "parallel" arrangement of valves 54 and 56, the alternative circuit in Fig. 12 employs valves 150 and 152 connected in series with each other. The valve 150 acts as a master on/off valve, and is coupled to the inlet bore 52. The output from the valve 150 feeds to the second valve 152, and also through a bypass path 154 to the second outlet 74 (which feeds to the fixed pressure regulator 82 in the third sub-unit 16c). The second valve 152 acts as a selector valve for selecting either a freeze mode (in which the valve 152 is open to allow high pressure fluid directly to the inlet of the instrument connector 22), or a purge mode (in which the valve 152 is closed, such that the fluid has to pass through the fixed pressure regulator 82).

The valve states for the different operating modes are shown in Fig. 14 (it being appreciated that the arrangement of the defrost valve 90 and the exhaust valve 92 remain unchanged).

It will be appreciated that, if desired, the position of the master valve 150 may be altered. For example, the valve 150 could be placed upstream of the variable pressure regulator 36 in the first manifold sub-unit 16a.

It will also be appreciated that, if desired, the master control valve 150 could be omitted altogether, and the variable pressure regulator 36 used instead as a manual control. This would require the user manually to reduce the pressure in the circuit to zero when appropriate. In general, the illustrated arrangements including at least four valves are preferred, as these allow the operator to leave the variable pressure regulator 36 at a desired level, and to terminate the flow of fluid simply by operating one of the open/close valves. However, removal of one of the valves would allow a three-valve circuit to be achieved, although at the inconvenience of the operator

16

having to manually adjust the variable pressure regulator 36 to shut off the supply of cryogen fluid.

Fig. 16 illustrates an alternative valve arrangement to replace the defrost valve 90 and the exhaust valve 92 in the third sub-unit 16c of the manifold (it being appreciated that a slightly different design of conduits within the manifold block 16c would be required to accommodate this alternative circuit). In Fig. 16, the separate defrost valve and the exhaust valve are replaced by a combined three terminal changeover valve 170. The "common" terminal 172 of the valve 170 is coupled to communicate with the output conduit 110 from the probe socket 22. One switched terminal 174 of the valve communicates with the port 98, and the other switched terminal 176 of the valve communicates with the port 100.

In this embodiment, it is possible to use a changeover valve 170 in place of two independent defrost and exhaust valves 90 and 92, because, as can be seen in Figs. 13 and 14, the states of the valves 90 and 92 are generally complementary. The only operating mode in which the valves might not have complementary states in the preceding embodiments is the vent mode. However, as explained previously, it is perfectly acceptable for the defrost valve to be closed during the vent cycle.

The use of a single valve unit 170 to replace individual defrost and exhaust valves 90 and 92 may provide even greater cost savings, and reduce assembly time.

As illustrated in Fig. 16, the resistance 138, and/or the leaky exhaust path 139 (including a resistance 138a) may be incorporated if desired to provide the improved defrost performance mentioned previously.

Fig. 17 illustrates a further modified valve arrangement for the third sub-unit 16c of the manifold (it being appreciated that a slightly different design of internal conduits within the manifold block 16 might be desirable). Fig. 17 is equivalent to the arrangement shown in Fig. 9 except that the defrost valve 90 and its associated conduits (ports 98 and 94) are omitted.

This circuit is believed to be suitable for low flow-rate probes, typically up to about 5 litres/minute. In order to defrost the probe, the exhaust valve 92 is closed, to shut-off flow to the exhaust socket. The resulting backing-up of pressure on the

17

exhaust side of the probe causes the pressure to equalise. and hence provide re-heating of the probe.

If desired, the leaky exhaust path 139 (including a resistance 138a) may be incorporated if desired to maintain a very small flow should this be necessary.

5 However, it will be appreciated that the resistance 138a would have to be very high (i.e. a very narrow constriction) in order for the pressure on the exhaust side to build up and hence provide the defrost function.

Although a multi-part manifold 16 has been described, it will be appreciated that, if desired, the manifold could be formed as an integral unit. Also, although the
10 illustrated manifold has a block form, it will be appreciated that any suitable shape and configuration of manifold may used as desired.

Fig. 18 shows, by way of example, a circuit implemented in a single-part manifold block 16d. The circuit may be as shown, or include features as shown, in any of Figs. 9, 12, 16 and 17.

15 It is emphasised that the foregoing description is merely illustrative of a preferred form of the invention. The skilled man will appreciate that many modifications may be made within the scope and/or principles of the invention. Features believed to of particular importance are defined in the appended claims. However, the Applicant claims protection for any novel feature or idea described
20 herein and/or illustrated in the drawings whether or not emphasis has been placed thereon.

CLAIMS

1. A cryosurgical control unit for controlling the flow of cryogen fluid through a cryosurgical instrument, wherein the control unit comprises a manifold defining a plurality of internal fluid flow paths and carrying at least one functional device communicating with a said internal flow path.
2. A unit according to claim 1, wherein the manifold is in the form of a block.
3. A unit according to claim 1, wherein the manifold is an assembly of sub-units.
4. A unit according to claim 3, wherein at least one of the sub-units is in the form of a block.
5. A unit according to claim 3 or 4, wherein the sub-units are secured to each other in face-to-face relation.
6. A unit according to claim 3, 4 or 5, comprising a seal device for forming a fluid-tight seal between two co-operating apertures in the sub-units, the seal device comprising a bridging tube, and an O-ring around the bridging tube.
7. A unit according to claim 6, wherein the O-ring seats in a recess in the face of at least one of the manifold sub-units.
8. A unit according to any preceding claim, wherein the control unit contains a fluid flow path circuit including a plurality of functional devices, at least a majority of the fluid circuit being implemented by means of the manifold.
9. A unit according to claim 8, wherein the manifold carries at least a majority of the functional devices.

10. A unit according to any preceding claim, wherein the manifold carries at least one pressure regulator.
- 5 11. A unit according to claim 10, wherein the manifold carries at least one fixed pressure regulator.
12. A unit according to claim 10 or 11, wherein the manifold carries at least one variable pressure regulator.
- 10 13. A unit according to any preceding claim, wherein the manifold carries at least one flow control valve.
14. A unit according to claim 13, wherein the manifold carries at least one
15 open/closed valve.
15. A unit according to any preceding claim, wherein the manifold defines a first flow path from an inlet connector through a variable pressure regulator to an instrument connector for communicating with the cryosurgical instrument.
- 20 16. A unit according to claim 15 or 16, wherein the manifold carries a first valve for controlling the flow through the first flow path.
17. A unit according to claim 15, wherein the manifold defines a second flow path
25 coupled to the first flow path, the second flow path passing through a fixed pressure regulator to said instrument connector.
18. A unit according to claim 17, wherein the manifold carries a second valve for
30 controlling the flow through the second flow path.

20

19. A unit according to any preceding claim, wherein the manifold defines an exhaust flow path from the or an instrument connector through an exhaust control valve to an exhaust connector.
- 5 20. A unit according to any preceding claim, wherein the manifold defines a pressure equalisation path from the delivery part of the or an instrument connector, through an equalisation control valve, to the exhaust port of said instrument connector.
- 10 21. A cryosurgical control unit for controlling the flow of cryogen fluid through a cryosurgical instrument, the control unit comprising a fluid flow path circuit including a plurality of functional devices, wherein at least a majority of the fluid circuit routing is implemented by means of a manifold defining a plurality of internal flow paths and carrying the respective functional devices for the circuit implemented by the manifold.
- 15 22. A cryosurgical control unit according to claim 21 which is operable to re-heat a J-T cryosurgical instrument by application of generally equal pressures of fluid to the inlet and exhaust channels of the instrument.
- 20 23. A cryosurgical control unit according to claim 22, comprising a valve for coupling together the inlet and exhaust channels of the instrument.
24. A cryosurgical control unit for controlling the flow of cryogen fluid through a cryosurgical instrument, wherein the control unit comprises a manifold defining a plurality of internal fluid flow paths including at least a first flow path and a second flow path, and the manifold carrying a connector for enabling the instrument to be releasably coupled in a fluid communication with said first and second flow paths.
- 25 25. A control unit according to claim 24, wherein said connector is received within said manifold.
- 30

26. A control unit according to claim 24 or 25, wherein the manifold carries a plurality of control valves for controlling the flow of fluid within the plurality of flow paths within said manifold.
- 5 27. A control unit according to claim 24, 25 or 26, wherein the manifold carries at least one pressure regulator for regulating the pressure of fluid in a predetermined flow path.
- 10 28. A control unit according to claim 27, wherein the pressure regulator is received within said manifold.
29. A cryosurgical control unit for controlling the flow of cryogen through a cryosurgical instrument, wherein the control unit comprises a manifold defining a plurality of internal fluid flow paths, and carrying at least one electrically operated valve for controlling the flow of fluid with a predetermined flow path, the valve being detachable from the manifold, wherein a seal is provided for forming a fluid-tight seal between the valve and a surface of the manifold.
- 15 30. A control unit according to claim 29, wherein said surface of the manifold is a smooth seal seat surface.
- 20 31. A cryosurgical control unit for controlling the flow of cryogen fluid through a cryosurgical instrument, wherein the control unit comprises a fluid circuit comprising:
- 25 an inlet conduit for receiving fluid into the circuit;
an outlet conduit for fluid for venting fluid from the circuit;
a connector for enabling a said cryosurgical instrument to be detachably connected to the circuit, the connector including a delivery port for delivering fluid to the instrument and an exhaust port for exhausting fluid from the instrument;

22

a first electrically operated valve arrangement coupled between the inlet conduit and the delivery port for controlling the flow of fluid from the inlet conduit to the delivery port;

a second electrically operated valve arrangement coupled to the exhaust port of the connector for controlling the flow of fluid through the exhaust port, the second valve arrangement being coupled to the outlet conduit;

32. A control unit according to claim 31, further comprising an electronic control unit for generating control signals to control the valve arrangements.

33. A control unit according to claim 31 or 32, wherein the first valve arrangement comprises a first electrically operated open/close valve, and the circuit further comprises a variable pressure regulator in series with said first open/close valve.

34. A control unit according to claim 33, wherein circuit further comprises a fixed pressure regulator coupled in a fluid path in parallel with said first open/close valve.

35. A control unit according to claim 34, wherein the first valve arrangement further comprises a second open/close valve coupled in series with at least the fixed pressure regulator.

36. A control unit according to claim 35, wherein said first open/close valve is coupled in a parallel flow path with respect to the second open/close valve.

37. A control unit according to claim 35, wherein said second open/close valve is coupled in a series flow path with respect to the first open/close valve.

38. A control unit according to claim 35, 36 or 37, wherein said first and second open/close valves of the first valve arrangement are operable independently of each other.

23

39. A control unit according to claim 33 or any claim dependent thereon, wherein the unit is operable in a freeze mode in which said first open/close valve is open.
40. A control unit according to claim 35 or any claim dependent thereon, wherein the unit is operable in a purge mode in which said first open/close valve is closed, and said second open/close valve is open.
41. A control unit according to claim 31 or any claim dependent thereon, wherein the second valve arrangement comprises a first open/close valve coupled between the exhaust port and the outlet conduit.
42. A control unit according to claim 41, wherein the second valve arrangement comprises a second open/close valve coupled between the delivery port and the exhaust port of the connector.
43. A control unit according to claim 31 or any claim dependent thereon, wherein the second valve arrangement comprises a changeover valve having a common pole coupled to the exhaust port, a first selectable pole coupled to the delivery port, and a second selectable pole coupled to the outlet conduit.
44. A control unit according to claim 31 or any claim dependent thereon, wherein the circuit comprises an equalisation fluid path selectable couplable between the delivery port and the exhaust port of the connector, to equalise the fluid pressures across the connector.
45. A control unit according to claim 44, wherein the equalisation path comprises a relatively high resistance to fluid flow, to control the rate of pressure equalisation.
46. A control unit according to claim 31 or any claim dependent thereon, further comprising an open high resistance fluid flow path coupled between the exhaust path

of the connector and the outlet conduit, whereby fluid is always able to leak through said open high resistance fluid flow path from the exhaust port to the outlet conduit.

47. A control unit according to claim 44 or any claim dependent thereon, wherein
5 the unit is operable in a defrost mode in which the second valve arrangement is operable to equalise the fluid pressures at the delivery port and the exhaust port of the connector.

48. A method of electronically controlling a fluid circuit in a cryosurgical
10 controller for controlling the supply of cryogen fluid through a cryosurgical instrument, the circuit comprising a first electrically operated valve arrangement for controlling the supply of fluid to the instrument through a high pressure path and a low pressure path, and a second electrically operated valve arrangement for
15 controlling the flow of fluid through an exhaust path from the instrument, and for controlling pressure equalisation across the delivery and exhaust sides of the instrument, the method comprising:

generating, in a purge mode, control signals to control the first valve
arrangement to supply fluid through the low pressure path to the instrument, and
control signals to control the second valve arrangement to exhaust the fluid from the
20 instrument, and to not equalise the pressure on the delivery and exhaust sides;

generating, in a freeze mode, control signals to control the first valve
arrangement to supply fluid through the high pressure path to the instrument, and
control signals to control the second valve arrangement to exhaust the fluid from the
instrument, and to not equalise the pressure on the delivery and exhaust sides; and

25 generating, in a defrost mode, control signals to control the first valve arrangement to supply fluid through the high pressure path to the instrument, and control signals to control the second valve arrangement to at least substantially prevent fluid from escaping through the exhaust path, and to equalise the pressures on the delivery and exhaust sides of the instrument.

1 / 13

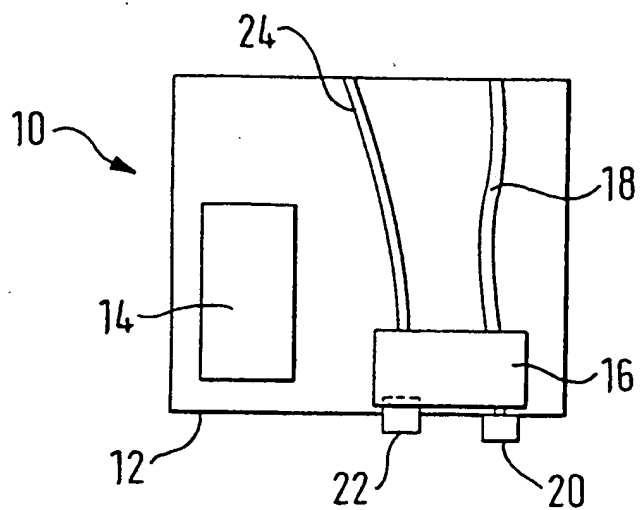


FIG. 1

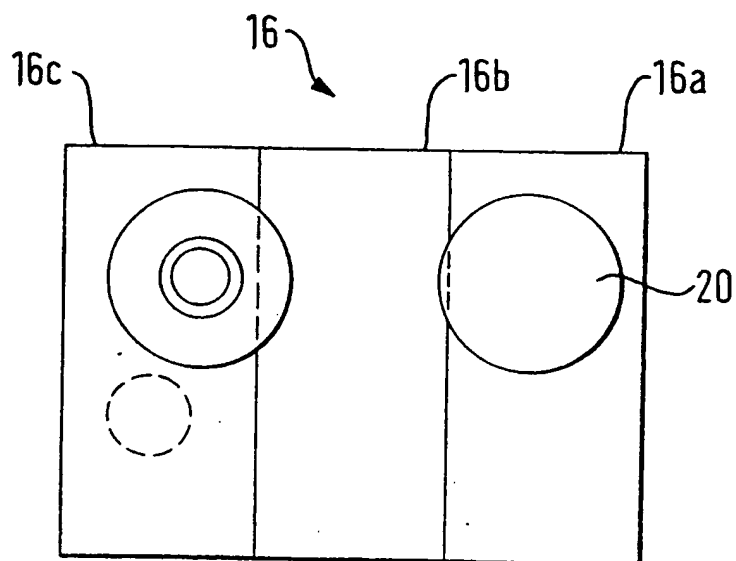


FIG. 2

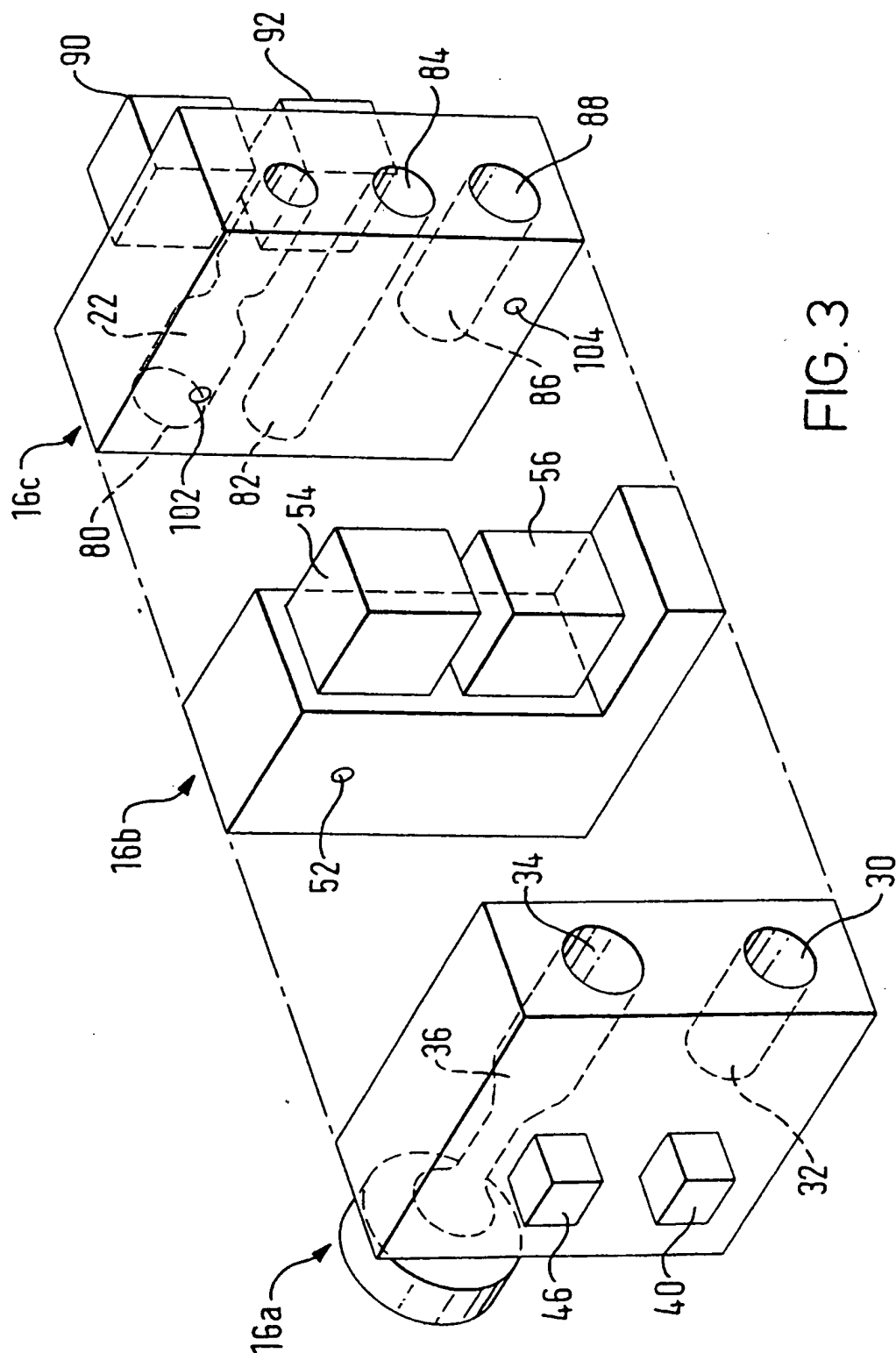


FIG. 3

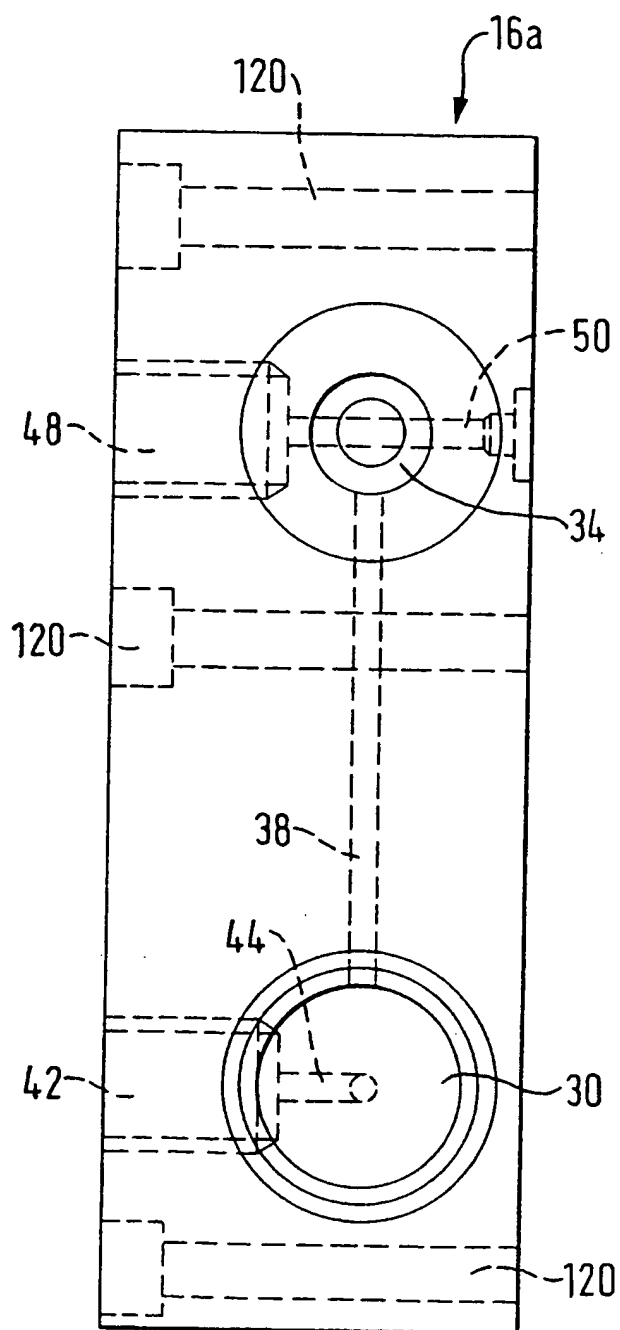


FIG. 4

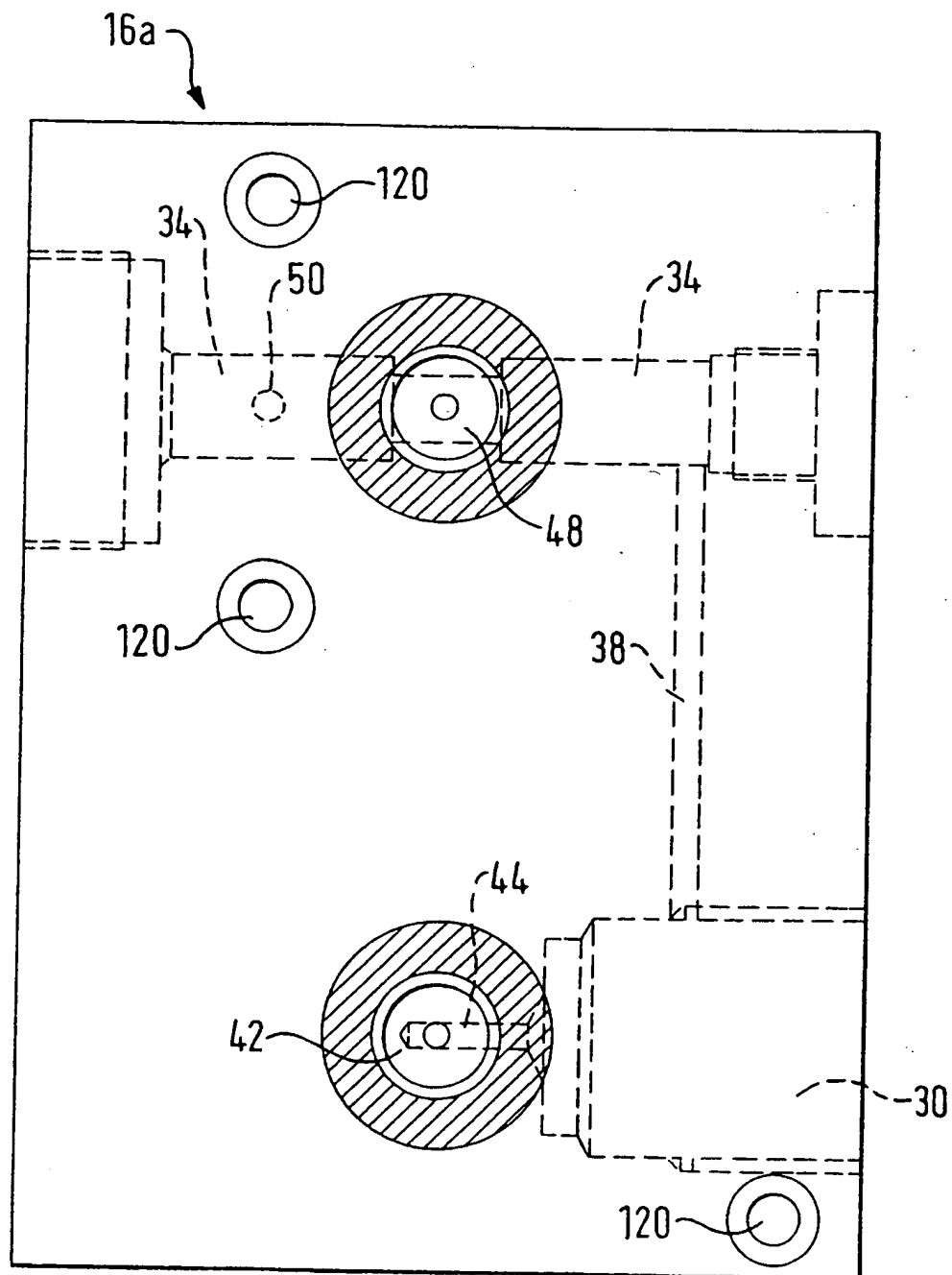


FIG. 5

5 / 13

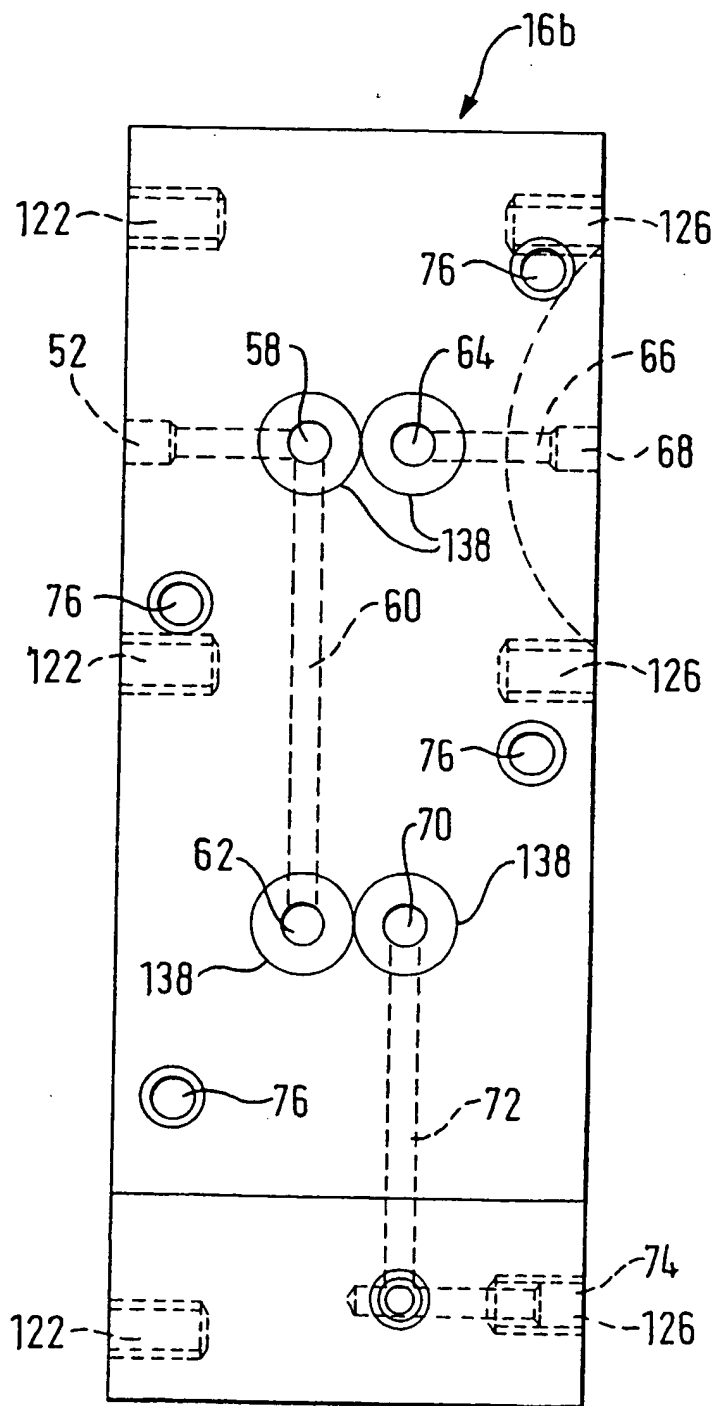


FIG. 6

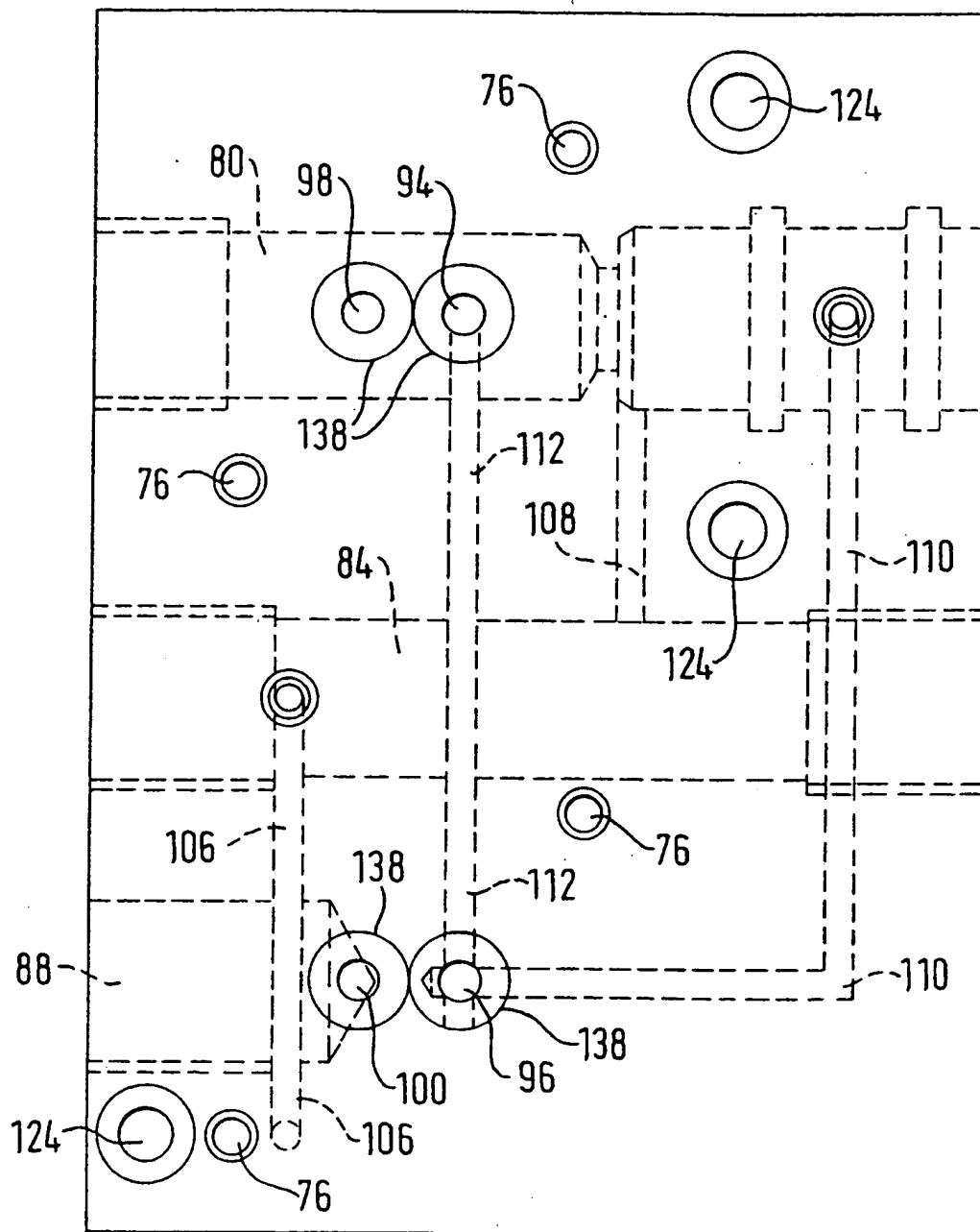


FIG. 7

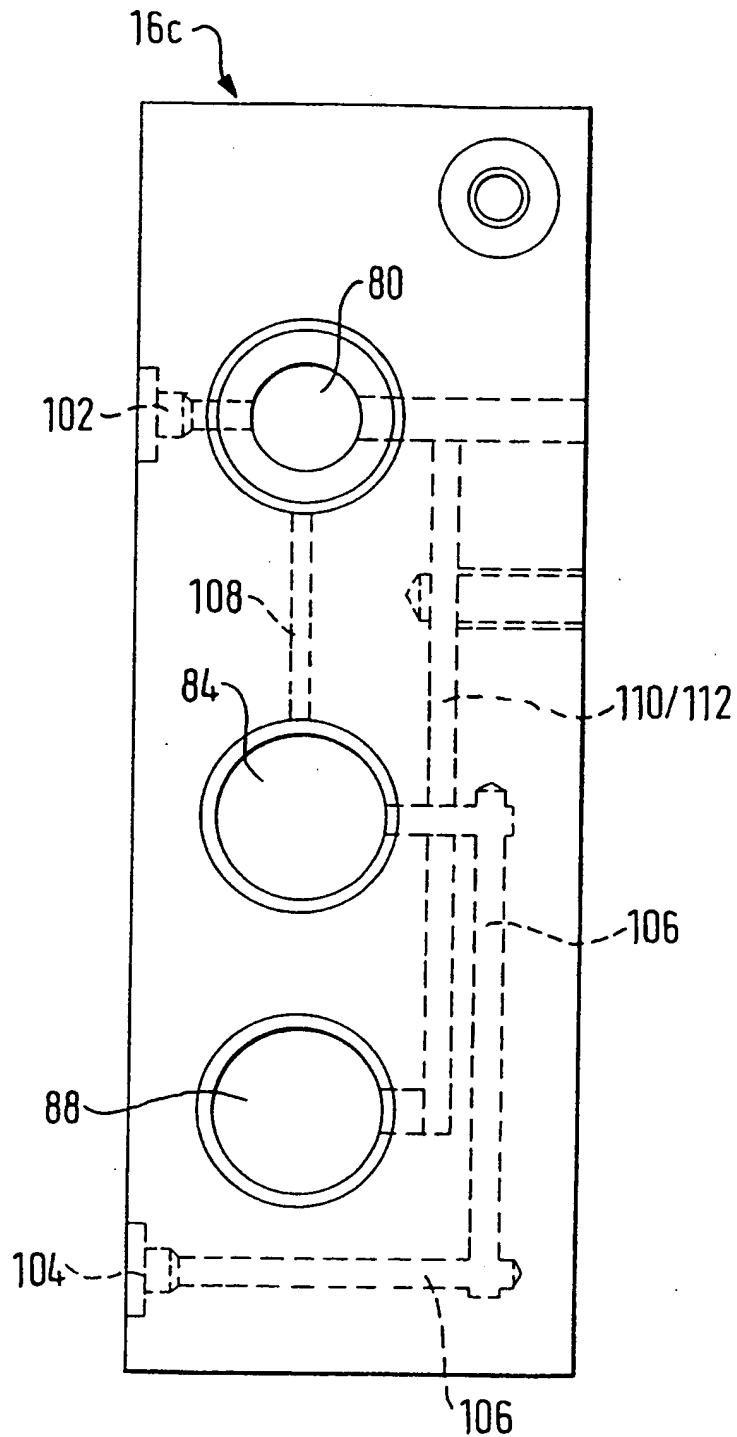


FIG. 8

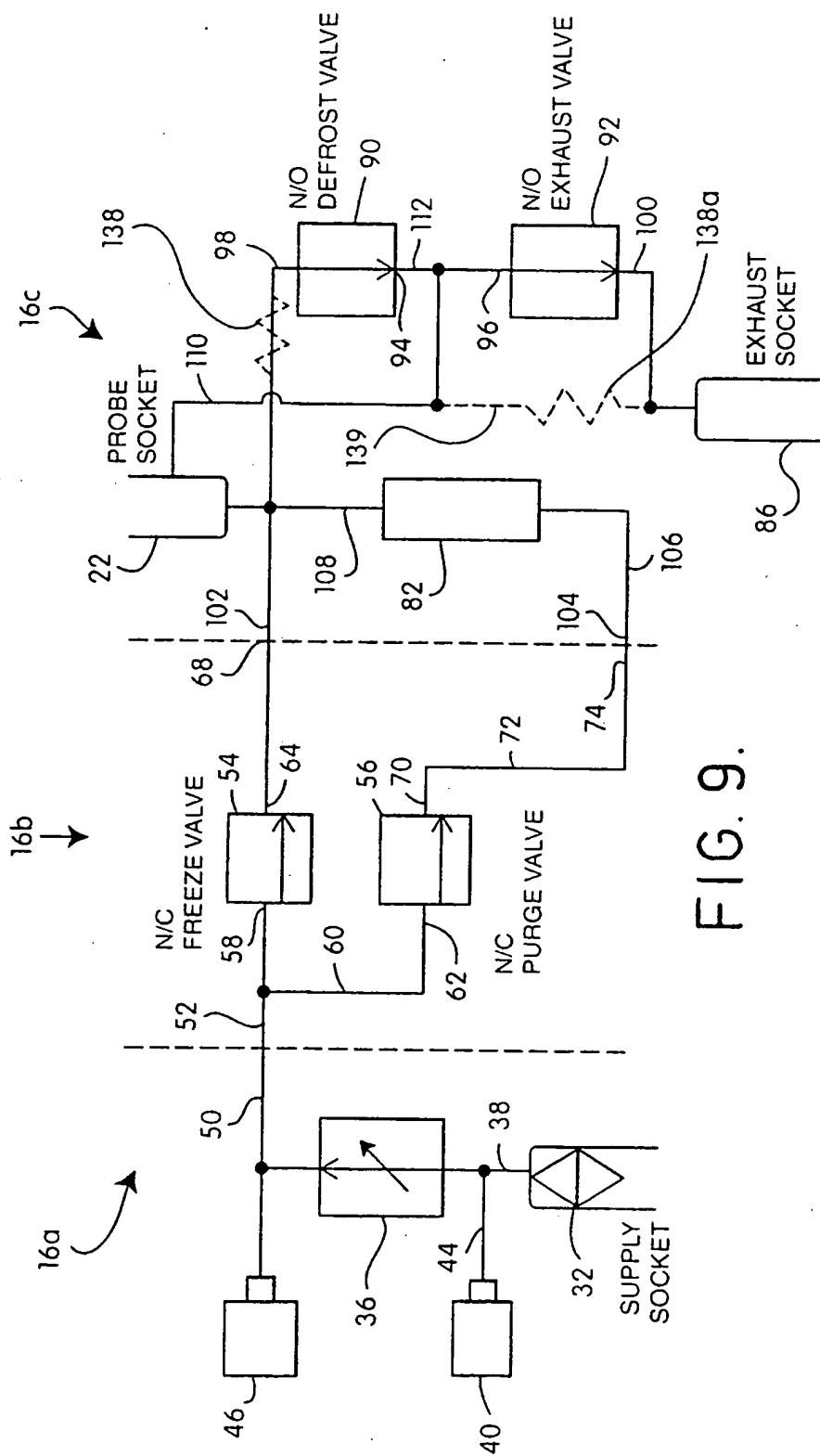
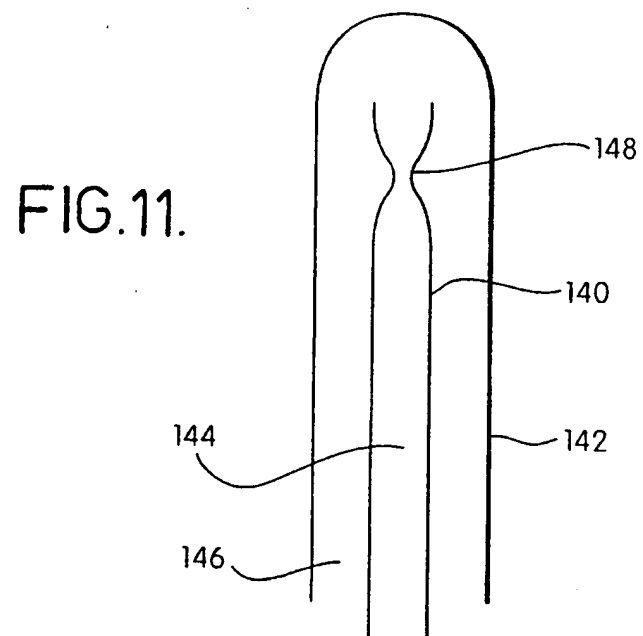
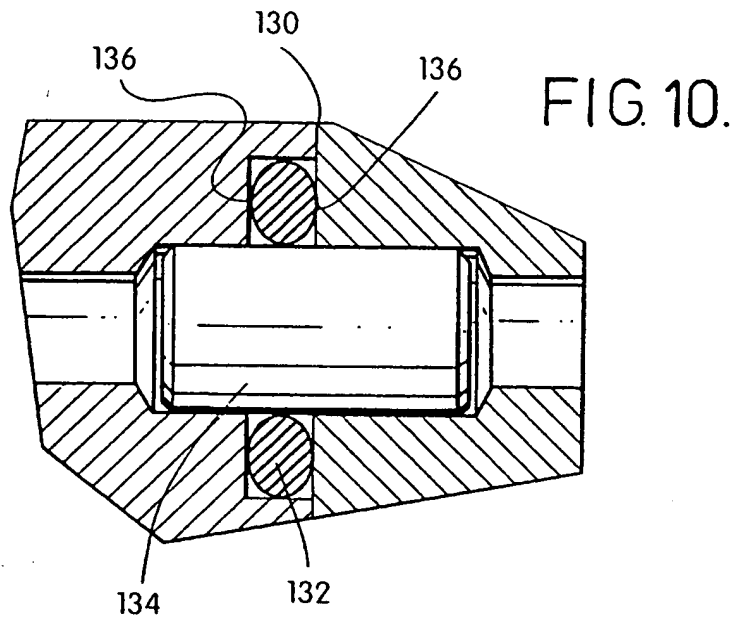


FIG. 9.



10 / 13

FIG. 12.

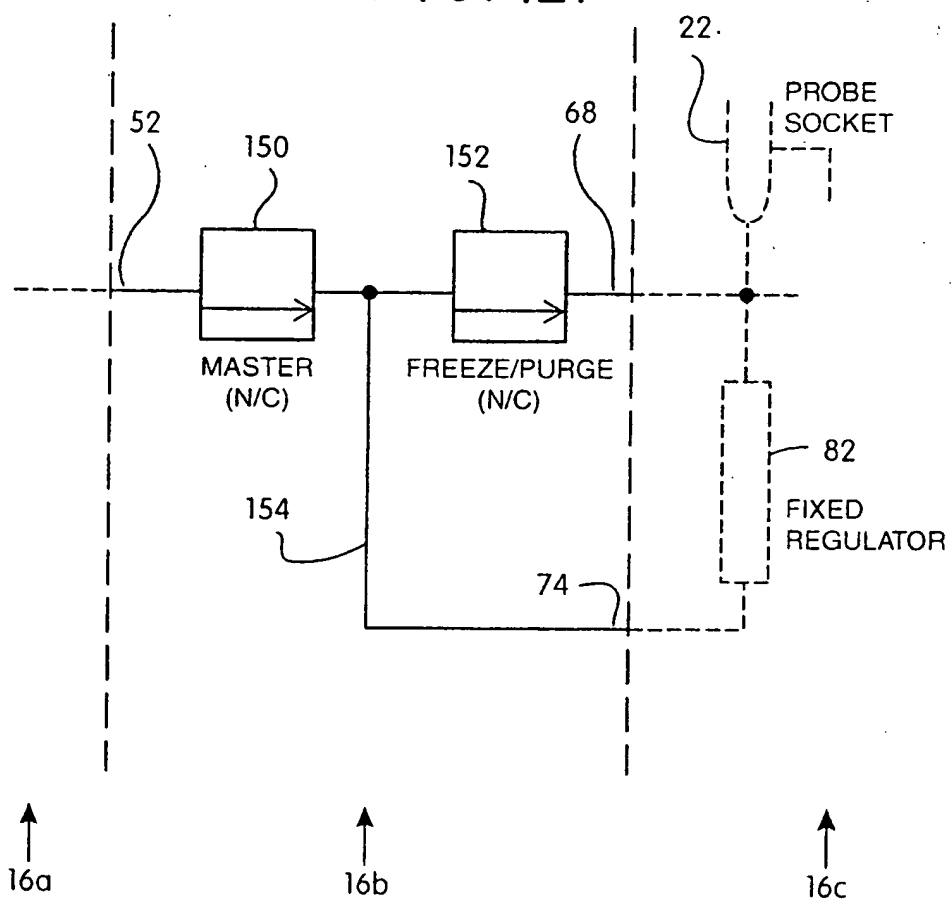


FIG. 13.

CYCLE ↓	VALVES			
	FREEZE 54	PURGE 56	DEFROST 90	EXHAUST 92
	PURGE	CLOSED	OPEN	CLOSED
	FREEZE	OPEN	(CLOSED)	OPEN
	THAW	OPEN	(CLOSED)	OPEN
	VENT	CLOSED	OPEN	CLOSED
		CLOSED	(OPEN)	OPEN

FIG. 14.

CYCLE ↓	VALVES			
	MASTER 150	FR/PU 152	DEFROST 90	EXHAUST 92
	PURGE	OPEN	CLOSED	CLOSED
	FREEZE	OPEN	OPEN	OPEN
	THAW	OPEN	OPEN	OPEN
	VENT	CLOSED	(CLOSED)	CLOSED
			(OPEN)	OPEN

12 / 13

